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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,398	01/21/2005	Zheng Xin Dong	113P/PCT3/US	5939

7590
Brian R Morrill
Biomeasure Incorporated
27 Maple Street
Milford, MA 01757-3650

12/27/2007

EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,398	Applicant(s) DONG ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 6-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5 is/are rejected.*
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6-10-05, 9-15-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-13 in the reply filed on 7-27-07 is acknowledged. Applicants also elected the species (Aib2, Glu3(NH-hexyl)hGhrelin(1-28)-NH₂). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that Applicants have requested rejoinder of the method Groups of II, III, IV, V, VI, VII. Applicants request is acknowledged. Applicants are reminded In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder. See MPEP § 821.04(b). In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. Failure to do so may result in a loss of the right to rejoinder. However, once the product claim is deemed to be allowable, the product claims will be rejoined and will be fully examined for patentability in accordance with 37 CFR1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. See MPEP 821.04.

A search was conducted for the elected species species (Aib2, Glu3(NH-hexyl)hGhrelin(1-28)-NH₂). This was found to be free of the prior art. In accordance with markush practice, the

prior art was extended to non-elected species and prior art was found that anticipate hGhrelin(1-28)-NH₂, of claim 5. Claims 1-2 and 5 read on the elected species. Claims 3-4 and 6-13 are withdrawn from consideration. It is acknowledged that claims 3-4 and 6-7 have been withdrawn even though they contain the elected species. However, these claims also contain species that have not been examined. The MPEP states If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.” For this reason, claims 3-4, 6-13 have been withdrawn as corresponding to non-elected species and claims 14-38 have been withdrawn as corresponding to non-elected groups.

Specification

2. The disclosure is objected to because of the following informalities: 37 CFR 1.821 requires Where the description or claims of a patent application discuss a sequence that is set forth in the “Sequence Listing ” in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by “SEQ ID NO: ” in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Appropriate correction is required.

Claim Objections

3. Claims 1-2 and 5 are objected to because of the following informalities: 37 CFR 1.821 requires Where the description or claims of a patent application discuss a sequence that is set forth in the “Sequence Listing ” in accordance with paragraph (c) of this section, reference must be made

to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (Biochem & Biophys. Researc Comm).

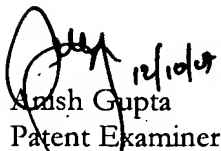
The claims are drawn hGhrelin analogs.

The reference teaches hGhrelin of the sequence GSS[O-CO-C7H15]FLSPEHQRVQQRKESKKPPAKLQPR (see page 144, table 1). This peptide meets the

limitation of claim 5 where the peptide claimed is hGhrelin(1-28). The difference between the reference and the instant application is that the reference does not specifically teach amidation of GSS[O-CO-C7H15]FLSPEHQRVQQRKESKKPPAKLQPR.

However, the reference does teach that amidation of the C-terminal carboxylic acid enhanced activity (see page 145). The reference illustrates this using 1-7 and 1-8 truncated analogs of Ghrelin. Therefore, it would have been obvious to amidate the native peptide because amidation of the C-terminal carboxylic acid enhanced activity. There would have been an expectation of success because amidation was shown in truncated analogs of Ghrelin to enhance activity. Thus, the amidated species is rendered obvious by the prior art.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.


Anish Gupta
Patent Examiner